

Remarks

I. Status of the Application and Claims

As originally filed, the present application had a total of 20 claims. These were cancelled in a Preliminary Amendment and new claims 21-45 were added. In a previous response to an Office Action, claims 40 and 42-45 were cancelled and, in the present response, claims 35, 37, 38 and 41 are cancelled. Thus, the claims now pending are claims 21-34, 36 and 39.

II. The Amendments

Claim 21 was amended to incorporate the requirements of claims 35, 37, 38 and 41. The amendments therefore do not add new matter to the application. Since all of the elements added by the amendments were already in the claims, they should already have been considered by the Examiner in searching the art. It is therefore respectfully requested that these amendments be entered.

The Rejections

In the present Office Action, a rejection of all claims under 35 USC §103 is maintained based upon Stucky (US 5,663,340) in combination with Daluge (US 6,552,193). The Examiner alleges that the '340 reference discloses the same reactions used by Applicants and that the reactions may be performed without added solvent. Although the reference does not teach the use of a Vilsmeier reagent in chlorination steps, this is allegedly provided in the reference by Daluge. The Examiner argues that one of skill in the art would be motivated to combine Stucky and Daluge to improve the overall method and that there are no other elements present that make Applicants' claims nonobvious.

Applicants respectfully traverse this rejection for the claims presented herein.

Applicants respectfully submit that there is an important aspect of the claimed process that has not fully been considered by the Examiner. In particular, Applicants' process includes a two step procedure that promotes the selective and controlled hydrolysis of groups at the 2 and 5 positions of intermediate compound II (see page 1 of the application for the structure).

As a result, a product is produced of much higher purity, albeit at a somewhat lower yield.¹ The prior art references cited by the Examiner both teach a single hydrolysis step in which conditions are uniformly maintained throughout. Adding a separate hydrolysis step performed under different conditions and demonstrating significantly improved product purity is clearly not suggested by the combined references and goes beyond the mere optimization of existing methods.

In Applicants' first hydrolysis step, water is added and the reaction mix is maintained at a temperature of 20-60°C without pH adjustment. In the second step, the pH is adjusted upward by the addition of inorganic base and the temperature is raised to 70-120°C. The degree to which the pH is changed between the two steps can be seen in Examples 1 and 2 of the application. Specifically, the pH was adjusted from -0.6 to 4.0 in Example 1 and from -0.5 to 3.6 in Example 2. The importance of hydrolysis conditions in terms of byproducts and yield is discussed on page 7 of the application, lines 1-9 and the advantage of Applicants' procedure in terms of products of high purity is demonstrated by Examples 1 and 2.

In addition, Applicants do not agree with the Examiner that Stucky teaches a process in which the purification of intermediates is omitted. In Example 1, the intermediate product of section 1.1 was clearly purified before the further steps of section 1.2 and Applicants have not been able to identify any other Examples or teachings in Stucky that should render the process presently claimed as obvious. Since there are no teachings in Daluge that would remedy this defect, it is submitted that one of skill in the art could not arrive at the process claimed by combining these references.

Conclusion

In light of the considerations above, Applicants respectfully submit that all of the Examiner's rejections have been overcome. It is therefore requested that these rejections be withdrawn and that the claims presently pending in the application be allowed.

¹ Evidence of increased purity is provided by comparing Examples 1 and 2 (processes according to the invention) with comparative Example 3. Example 1: purity 98.7%, yield 39.5%; Example 2: purity 97.6%, yield 37.4%; Example 3: purity 83.8%, yield 45.7%.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicants' undersigned attorney at (240)683-6165.

Respectfully submitted,

LAW OFFICE OF MICHAEL A. SANZO

By: /Michael A. Sanzo/
Michael A. Sanzo
Reg. No. 36,912
Attorney for Applicants

Date: July 21, 2008
15400 Calhoun Drive, Suite 125
Rockville, Md. 20855
(240)683-6165